DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

9119941

APR 2 2001

WARNING LETTER

Ref:OC:I1-1894

Mr. Richard Mullen
Group Manager
Safety & Compliance Consulting
29 Sweetman Lane
West Melford, New Jersey 07480-2932

via FEDERAL EXPRESS

Dear Mr. Mullen:

This letter is addressed to you as requested in your letter of January 3, 2001. It is written to advise you of items of noncompliance with the laser performance standard encountered during review of the product report (accession Number 0022806-00) submitted for the Poe Lang Laser Heat Sensor Model HS-3xxx series.

The report indicated the products being reported are available in two models, Model 3000 and 3500. From the report we have concluded that the Model 3000 incorporates a laser diode emitting laser radiation in only the visible wavelength of 630-680 nm at a maximum output of 5 mW.

The Model 3500 in addition to the 630-680 nm laser diode incorporates a second laser diode emitting a maximum of 5 mW laser radiation at 830-860 nm, an invisible wavelength. The manufacturer has classified these two products as Class IIIa.

These products are considered alignment laser products and are subject to the requirements of paragraphs 21 CFR 1040.11(b), Alignment Laser Products. This paragraph prohibits alignment laser products from emitting infrared radiation in excess of the Class I limit for the applicable wavelength. In this case the applicable Class I limit for a laser product in the 830-860 nm range is 70 to 80 microwatts. At 5 mW the Model 3500 far exceeds this limit.

Because the Model 3500 exceeds the Class I limit it is non-compliant with paragraph 21 CFR 1040.11(b). When classified in accordance with paragraph 21 CFR 1040.10(c) the Model 3500 would properly fall into Class IIIb.

In addition to being non-compliant with 21 CFR 1040.11(b) and 1040.10(c), the Model 3500 failed to comply with at least the following performance and or labeling requirements for a Class IIIb laser product, if it could be so classified.

1. 21 CFR 1040.10(f)(3): Remote interlock connector. The Model 3500 failed to incorporate a remote interlock connector.

2. 21 CFR 1040.10 (f)(4): Key control. The Model 3500 failed to incorporate a key control.

3. 21 CFR 1040.10(f)(6): Beam attenuator. The Model 3500 failed to incorporate a compliant beam attenuator. (see item below)

4. 21 CFR 1040.10(g)(1)(iii): Labeling requirements. The warning logotype incorrectly stated the product was Class IIIa and failed to include the proper warning including the word "invisible" in position 1 of this label as required by 21 CFR 1040.10(g)(8)(ii).

The following observations are applicable to both models of this product:

1. 21 CFR 1040.10(h)(1)(iv): User information. The user information failed to include the statement "Caution - use of controls or adjustments..." required by this section.

2. 21 CFR 1040.10(h)(2)(ii): Purchasing information. The report failed to include any sales and or other material used to promote sale of these products. This information is necessary to confirm compliance with this paragraph.

The following item needs clarification:

Item 7.7.1 of the report states that the device is equipped with a momentary on switch. The presence of this type switch and its mode of function is used as justification for requesting in Item 7.9.1 use of this switch as an alternate means of providing the beam attenuator requirements of paragraph 21 CFR 1040.10(f)(6). However, the user instructions imply this switch requires separate action for turning it on or off. Please clarify this apparent conflict of information.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum penalty of $300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged failures to comply do not exist.

2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).

3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

   a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.

   b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into commerce.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a copy of your response to: Director, Compliance Branch, Atlanta District Office, Food and Drug Administration, 60 Eighth St. SE District, Atlanta, GA 30309. If you have further questions on these requirements, please contact Frank Mackison of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

Christy Foreman for

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health